Attributes of Exemplary Research

The Clinical Research Team

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Staff is one of the most important, yet expensive, components of a research program. Of the total time and effort required to conduct a clinical trial, nurses and data managers each contribute > 30% of the time, whereas physicians account for only 9%.[1] Although investigators appreciate the research team's value, they are often uncertain about how to properly develop and manage the team.

To help investigators develop the required knowledge and skills to run a clinical research program, *Journal of Oncology Practice* (*JOP*) chose to publish several articles on this topic. This article is part of the series on exemplary attributes of clinical trial sites, highlighting the attributes of sites conducting quality clinical trials.[2]

In the most recent issue of *JOP* is an original research article reporting on the Ontario Protocol Assessment (OPAL) tool, which is an evidence-based tool for assessing trial complexity and associated workload.[3] The OPAL tool is an important addition to the field because it accounts for trial complexities that were not addressed in workload tools developed in previous decades.

Delegation of Research Tasks

A research site's principal investigator is responsible for oversight of clinical trials but can delegate research tasks to appropriately trained staff (investigator responsibilities are discussed in the previous article in the *JOP* series on exemplary attributes).[4] Matching individuals with suitable tasks ensures that the program's resources are being used appropriately and that staff enjoy and remain challenged by their responsibilities.

Knowing what task can be delegated to individuals on the research team can be challenging because it varies on the basis of an individual's experience and licensure. A research team may include clinical research associates (CRAs), research nurses, data managers, and study coordinators. Depending on a program's organizational structure, the responsibilities assigned to each may differ greatly from one research program to another, both within and outside the United States. Tasks assigned to the staff include screening for potential study candidates, determining eligibility, coordinating the patient calendar, preparing documents for submission to institutional review boards, filing amendments, submitting safety data, conducting patient education, obtaining informed consent, and assessing potential adverse events. When resources permit, it is also helpful to have a manager or coordinator who supervises the program by overseeing quality assurance, staffing, budgeting, and site audits.[5] This person will work closely with the primary investigator to ensure that all investigator responsibilities are being met. A common mistake to avoid is delegating tasks to someone who is overqualified, such as assigning the task of photocopying to a registered nurse. Poor delegation leads to inefficient use of the program's resources and may cause staff to become dissatisfied with their duties. The clinical research manager can help ensure that tasks are being delegated appropriately.

Once tasks have been delegated, many sites will use a delegation log to document which staff person has been delegated each specific study task (Figure 1). A delegation log should be completed for each study open at the site, because staff responsibilities often vary among trials. The site should also keep documentation of training modules that have been completed by each staff member. Training logs might be divided into (1) training that must be completed by new members of the research team (Figure 2), and ongoing training that must be maintained by the entire research team (Figure 3). Standard operating procedures (SOPs)[6] that address training requirements can further document the process and ensure it is sustainable. In addition to pursuing basic research training requirements, CRAs and research nurses should be encouraged to pursue specialty certification because instruction about conducting clinical research is generally not taught in health science or nursing education programs. Certifications are offered by the Society of Clinical Research Associates[7] and the Association of Clinical Research Professionals.[8]

It is most effective when research staff are assigned solely to the research program. For example, if the research program can only support 0.5 full-time equivalent research associates/nurses, then the program should hire a part-time employee whose sole responsibility is to perform research. When one position is split between both research and clinical practice, the research tasks often get neglected.

The Extended Research Team

The research team extends well beyond the individuals who are directly employed by the research program. For example, infusion nurses are generally not on the payroll of the research

Clinical Trials Support Unit
Task Delegation and Signature Log

Protocol Number:					Site Address:		
Investigator Name:							

Print Name	Signature	Initials	Study Role	Key Delegated Tasks	Dates	
					From	To

Delegated Tasks:

1. Obtain Informed Consent	7. Ongoing AE Assessment
2. Obtain Medical History	8. CRF Completion
3. Perform Physical Exams	9. Data Edits
4. Inclusion/Exclusion Assessment	10. Lab Specimen Shipment
5. Drug Dispensing	11. Update/Maintain IRB documents
6. Drug Accountability/Reconciliation	12. Other

Signature of Investigator:	Date:

Figure 1. Clinical Trials Support Unit task delegation log. AE, adverse event; CRF, case report form; IRB, institutional review board. From Hospital for Sick Children, Toronto, Ontario, Canada. Adapted with permission.

program but are often responsible for administering investigational drugs and monitoring trial participants during infusion of the agent. The same is true of pharmacists, who may or may not be employed directly by the research program. It is important that pharmacists who support the research program receive training regarding drug accountability, because requirements vary greatly between standard practice and clinical research. There are also administrative roles that might be delegated to individuals external to the research program, such as billing and contracting. Patient navigators and advocates also play a critical role at many clinical research sites. Collaboration among all individuals who support the clinical research program will enable the full potential of the program to be realized.

Physician colleagues are vital to the success of the research program even when they are not listed as an investigator on the protocol. Surgeons, pathologists, radiologists, and many other specialists play an integral role in the conduct of quality clinical trials. It is important that all of these individuals are knowledgeable about the requirements of clinical trials to which they will be contributing, especially specific laboratory or diagnostic imaging requirements. The site's clinical trial implementation process should include collaboration with these specialists, who provide invaluable perspective regarding the feasibility and site-specific logistics of the protocol requirements.[9] Outreach to primary care providers is also important. Every physician who interacts with a patient can influence the patients' understanding and desire to participate on clinical trials.

Because the direct benefit of clinical research may not be apparent to all medical professionals, efforts to promote support among staff are essential. Awareness about clinical trials needs to occur at all levels of the institution and should be incorporated in the mission and vision of the site. For some professionals, education and awareness activities can make a positive impact on their willingness to contribute. This can be done via in-person meetings in which individuals can connect with the research team and have their questions answered. Clinical professionals should also be educated about specific trials open at the site. For example, an informal lunch might be held to educate infusion nurses about current clinical trials open at the site and any special requirements associated with infusion of the investigational agent and potential adverse effects for which patients should be monitored.

Beyond education, there are several other ways to promote staff support of the research program, such as discussing how

New CRA Training Log		
Employee Name:		Employee ID:
Item		Date Completed
General Overview		
Clinical Trials Support Unit Overview	One-on-one training	
Privacy	Review P&P	
Hospital Systems		
Divisional Database Training	One-on-one training	
Electronic health record system training, inperson	Lecture	
Electronic health record system training, online	Online Module	
Imaging System Training	Lecture	
Research Participant Related		
Patient enrollment (biology & treatment)	One-on-one training *Eligibility & Enrollment SOP*	
Data (followup & on treatment)	One-on-one training *AE SOP*	
Adverse Event Reporting (AdEERs)	WebEx Training *AE SOP*	
Procuring specimens	One-on-one training	
Consenting (study dependent)	One-on-one training *CRAs Consenting SOP*	
Regulatory Related		
Opening a new study	One-on-one training *Opening a New Study SOP*	
Processing a study amendment	One-on-one training *Amendment Processing SOP*	
Annual Renewal	One-on-one training	
AE/Safety report submission	One-on-one training *AE SOP*	
SOP	Review of all currently approved SOPs	
*Training Logs & certificates are maintained centrally (personnel file/electronically) *New CRAs will also complete the CRA Core Training Log		

Figure 2. Training log for new clinical research associates (CRAs). P&P, policies and procedures; SOP, standard operating procedure; AE, adverse event. From Hospital for Sick Children, Toronto, Ontario, Canada. Adapted with permission.

the research program can be a source of revenue for various departments. For example, although a special laboratory test may require increased effort on behalf of the staff in the laboratory, it might also represent a new way for the lab to generate income. Because private trial sponsors usually reimburse at cost, reimbursement for the tests might be higher than what is paid by third-party payers. Physician colleagues might also benefit from discussions about how the clinical research program can contribute to research that is important to them. For example, a pathologist who conducts basic or translational research might volunteer time to the clinical research program because specimens that are collected for the purpose of research ultimately enable the progress of the pathologists' research. Working collaboratively and understanding the opinions and needs of colleagues at the site will promote a culture of clinical research.

Promoting Staff Satisfaction

Even in a challenging economy, a number of things can be done to promote staff satisfaction and maintain, or improve, staff retention. Foremost, it is important that the program's leadership show respect and esteem for all staff. This can be done by listening to staff concerns, showing interest, and engaging staff in decision making. Engaging staff not only improves staff satisfaction, but it also helps the program make more informed decisions. For example, sites that engage staff in the selection of new trials promote a team culture within the site while also benefiting from perspectives that may be outside the physicians' scope, such as determining the feasibility of completing certain protocol-required testing at the site.

Encouraging staff to attend research meetings and participate in professional development activities also promotes staff satisfaction while maintaining quality within the program. Possible professional development activities may include attending meetings of the site's National Cancer Institute Cooperative Group affiliation or participating in sessions offered by a professional society. Professional development may also meet requirements for an individual's licensure or certification. A research program should develop a policy on how costs associated with continuing education will be managed, then budget

Core Training Log			
Employee Name:		Employee ID:	
Item		Date Completed	General Overview
Tri-Council Policy Statement Training	TCPS Online Module		N/A
NIH – Human Participants Protection Education for Research Teams	NIH Online Module		N/A
COG CRA Modules	CRA Modules		N/A
GCP	GCP Module Lecture		Annual
Saf-T-Pak Training	Module & Quiz		
Accessibility Standards Training Program	Online Module		N/A
Fire Training	Online Module Lecture		Annual
CCRP Certification	Examination		Recertification Q 3 years
COG Conflict of Interest	COG online		Annual in January
*Training Logs & certificates are maintained centrally (personnel file/electronically)			

Figure 3. Training log for clinical trials core tasks. TCPS, Tri-Council Policy Statement; NIH, National Institutes of Health; COG, Children's Oncology Group; CRA, clinical research associate; GCP, good clinical practice; CCRP, certified clinical research professionals. From Hospital for Sick Children, Toronto, Ontario, Canada. Adapted with permission.

accordingly. Costs associated with continuing education include registration fees, travel, and staff time away from the office.

Developing an internal promotion system is also a valuable way to retain employees. Some sites do this by creating different tiers within each position title. Under this system, a new CRA generally begins at an entry level and is responsible for tasks that are suited to their level of skill and training. As the individual progresses, they may be promoted to a midlevel position, and eventually to a senior-level position. A tiered system prevents new staff from becoming overwhelmed and ensures that senior staff remain engaged and challenged.

Professional accomplishments and recognition are also very important for staff satisfaction. When possible, sites should provide coauthorship opportunities to CRAs and nurses who had an integral role on the study. Staff may also play an important role in conceptualizing and developing certain research projects, such as cancer control studies or research regarding trial accrual. Even when coauthorship opportunities are not possible, leaders of the program should be certain to disseminate information about the outcome of any research to which the site's team contributed, such as articles reporting the results of multicenter trials that were open at the site.

Preparing for Staff Turnover

With adequate preparation and cross-training, staffing changes can have a minimal impact on the research program and provide an opportunity for the program to welcome new employees who bring additional skills and perspective to the team. An important way to prepare for staff turnover is to cross-train staff so more than one person knows how to conduct each task. This can be done both formally and informally; for example, double-checking colleagues' work for quality assurance is an informal way the entire team can become familiar with all projects being conducted at the site.

It is also important to fill open positions wisely. First, consider whether it is possible to promote from within the program to fill the position. When hiring new staff, be certain to look beyond their experience to determine whether an individual is going to be good fit for the program. Because of the expense and time needed to train new staff, it is important to find individuals whose attitude and work ethic meet the needs of the program.[10] Also, a manager should use this staffing change as an opportunity to review position descriptions at the site and determine whether each position provides the opportunity for staff to make important contributions to the program. If this is not the case, then modifications should be made. No one person, including a new employee, should be delegated all the unpleasant tasks of the program. If this happens, dissatisfaction is likely to occur and can lead to frequent staff turnover.

Summary

Developing and maintaining an exemplary research team is essential to the success of a quality clinical research program. Functions such as regulatory compliance, protocol maintenance, patient care, tissue acquisition and transmittal, data collection and submission, and general administration are among the many tasks on which quality clinical research, protection of subjects' rights, and advancement of science depend. No single individual could expect to fulfill all of these tasks.

Effective management requires shared commitment to excellence, mutual respect for each team member's role, and effective communication. Once staff members are trained and data management systems are implemented, this infrastructure has to be maintained and refreshed continually. Ultimately, a leader of an effective research program must acknowledge the value of each of its members while promoting a culture of teamwork and commitment to delivering high-quality care to patients.

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